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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/618,577 | 07/18/2000 | Jean A. Setterstrom | Army 145 | 9378 |
| 7590 | 02/11/2004 | | EXAMINER | |
| Caroline Nash Nash & Titus LLC 3415 Brookeville Road Suite 1000 Brookeville, MD 20833 | | | ROBINSON, HOPE A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1653 | |

DATE MAILED: 02/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 09/618,577 | Applicant(s) SETTERSTROM ET AL. | |
| | Examiner Hope A. Robinson | Art Unit 1653 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-168 is/are pending in the application.
- 4a) Of the above claim(s) 1-41 and 49-157 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 42-48 and 158-168 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's election of Group II (claims 42-48 and 158-168 with *E. coli* as the pathogenic organism, bacterial infections as the disease and SEQ ID NO: 28 as the active agent), without traverse on December 11, 2002 is acknowledged. It is noted that applicant filed amendments to the specification on November 10, 2003.
2. Claim 42 has been amended. Claims 158-168 have been added. Claims 1-168 are pending. Claims 42-48 and 158-168 are under examination.

Priority

3. Applicant submitted amendments to the specification filed on July 18, 2000 which corrected the priority information to include the divisional application 09/789,734, now U.S. Patent No. 6,309,669. However, Applicants amended the specification again on November 10, 2003 requesting that the Patent Office delete the present paragraphs and insert new paragraphs pertaining to the priority documents, and the above divisional was left off the list.

Correction is required.

Basis For NonStatutory Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 42-48 and 158-168 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,528,097. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are directed to an a process for preparing controlled release microcapsule formulations characterized by burst-free, sustained, programmable release of non-steroidal anti-inflammatory drugs. The instant application is directed to a process for preparing controlled release compositions characterized by burst-free, sustained, programmable release of biologically active agents. The dependent claims indicate that the agent is a polypeptide. Although the claims in the patent and the instant application differ in scope, the patented claims are encompassed within the scope of the present application claims. Therefore, the two sets of claims are obvious variations of each other and the instant application is merely an extension of the patented claims.

This is an obvious-type double patenting rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 42-48 and 158-168 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 and the dependent claims hereto are indefinite because the claim recites in line 2 "biologically active agents" and in line 4 "biologically active agent or active core" which lacks antecedent basis with regard to an "active core" not previously mentioned in the method steps (see also claim 46).

Claim 43 is indefinite because the claim recites "innter" in line 2 in association with the emulsion and it is unclear what is being referred to.

Claim 44 is indefinite for the recitation of "high encapsulation efficiency" as the term "high" is relative and does not quantify the degree of efficiency intended in the claimed invention (see also claim 48).

Claim 45 is indefinite because the claim recites "(o/s)" to signify "oil-in-water" which was previously captured in independent claim 42 as "(o/w)". Note that the claim also recites "a oil-in-water emulsifier" instead of "an oil-in-water emulsifier". The dependent claims hereto are also included in this rejection.

For clarity the language "(starting sequence # given)" should be deleted from claim 161 as this is not a limitation to the claim.

Claim 162 is indefinite because the claim recites "wherein release profiles of variable rates and duration are achieved" because the metes and bounds of the claim is undefined as it is

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unclear what release profiles produce what variable rates/duration. See also the language "different ratios" which are not set forth in the claim.

Claim 163 is indefinite because the claim recites "polymer is increased, the release rate of active ingredient increases" and there is no indication of how much of an increase in the polymer results in what percent increase in the active ingredient which is also undisclosed.

Claims 166-168 are indefinite because the claims recite "relative ratio", and the term relative does not definitely quantify the ratio which is the limitation of the claimed invention.

Conclusion

Allowable Subject Matter

7. Claims 42-48 and 158-168 are free of the prior art. The prior art teaches oral-intestinal vaccines against enteropathogenic organisms using antigens encapsulated within biodegradable-biocompatible microspheres and the use of CFA/I as the active agent (see for example Reid et al., WO 92/19263), however, the prior art is silent on burst-free, sustained, programmable release of biologically active agents and the process as described in the instant application claim 42.

8. No claims are allowable.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday-Friday from 9.00 am to 5.30 pm (EST).

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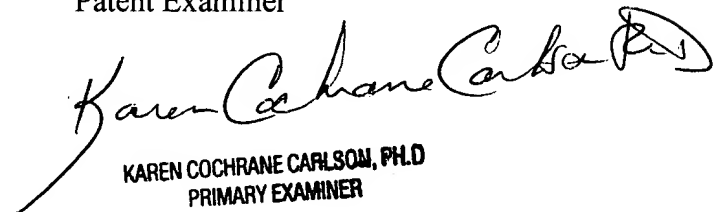
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low, can be reached at (703) 308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope Robinson, MS 

Patent Examiner


KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER